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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,544	10/29/2003	Anthony W. Confer	57188/02-774	7788
22206	7590	12/30/2004	EXAMINER	
FELLERS SNIDER BLANKENSHIP BAILEY & TIPPENS THE KENNEDY BUILDING 321 SOUTH BOSTON SUITE 800 TULSA, OK 74103-3318			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/696,544

Applicant(s)

CONFER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>71204</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

DETAILED ACTION

Election

- 1) Acknowledgment is made of Applicant's election filed 09/07/04 of invention I, claims 1-5, drawn to a vaccine, and the species, PlpE protein of SEQ ID NO: 2, in response to the restriction and the species election requirement mailed 08/03/04. Applicants have elected without traverse.

Status of Claims

- 2) Claims 1-8 are pending.

Claims 4-8 have been withdrawn from consideration as being directed to a non-elected invention or a non-elected species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-3 are under examination. A First Action on the Merits is issued for these claims.

Sequence Listing

- 3) The raw sequence listing submitted in this application has been entered on 11/10/2003.

Information Disclosure Statement

- 4) Acknowledgment is made of Applicant's Information Disclosure Statement filed 07/12/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Oath/Declaration

- 5) The oath/declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath/declaration is defective because, non-initialed and/or non-dated alterations have been made to the oath or declaration (see page 4). See 37 C.F.R 1.52(c) and 1.57.

Priority

- 6) This instant application claims domestic priority to the provisional application, SN 60/422,305, filed 10/30/2002.

Specification - Informalities

- 7) The specification of the instant application is objected to for the following reasons:

(a) To be consistent with the drawings for Figures 4A-4C, in section [0020] of the instant specification, Applicants should refer to 'FIG 4' as --Figures 4A to 4C--.

(b) The use of the trademark in the instant specification has been noted. For example, see section [0029]: 'Invitrogen' and 'ProBond'; sections [0052] and [0053]: 'BioRad'; and sections [0034] and [0035]: 'Pfizer' etc. Each letter of the trademark must be capitalized. See also section [0056] for limitations such as 'Tween-20' and 'Triton-X-100'; and Figures 2-5 for limitations 'Pulmoguard'; 'Presponse' and 'Poly-Bac'. The recitations should be capitalized wherever they appear or be accompanied by the generic terminology. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

(c) The amino acid sequence recited in line 11 on page 26 contains more than four amino acids, yet is not identified by a SEQ ID number as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

Rejection(s) under 35 U.S.C § 112, Second Paragraph

8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

9) Claims 1-3 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1 and 3 are vague and indefinite in the limitation 'M.', because it is unclear what does the letter 'M' stand for. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the letter in the base claim with the expanded term that it

appears to stand for, i.e., *Mannheimia*--.

(b) Claim 3 is vague in the limitation 'polypeptide of SEQ ID NO: 2' without distinctly reciting that the SEQ ID NO: 2 represents --the amino acid sequence of SEQ ID NO: 2--.

(c) Claims 2 and 3, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

10) The following is a quotation of the appropriate paragraph(s) of 35 U.S.C. § 102 that form the basis for the rejection(s) under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11) Claims 1-3 are rejected under 35 U.S.C § 102(b) as being anticipated by Pandher *et al.* (*Infect. Immun.* 66: 5613-5619, December 1998 -- Applicants' IDS) as evidenced by Hunter (US 5,554,372) or Berinstein *et al.* (US 20040033234).

The term 'vaccine' represents the intended use of the claimed protein and therefore is not given any patentable weight in this rejection.

Pandher *et al.* taught a composition comprising PBS and a recombinant PlpE outer membrane protein of *P. haemolytica* comprising the amino acid sequence of SEQ ID NO: 2. The protein is expressed via a recombinant *E. coli* (see abstract; Materials and Methods; Figure 1 and 2; and Results). The PlpE is taught to be immunogenic in cattle (see abstract). A sequence search performed at the Office demonstrated that the prior art amino acid sequence has 100% sequence identity with the instantly recited recombinant *M. haemolytica* PlpE outer membrane protein of SEQ ID NO: 2 (see sequence search report). Although the prior art does not refer to the protein as the recombinant PlpE of '*M. haemolytica*', because of its structural identity with the prior art protein, the instantly recited protein of SEQ ID NO: 2 is viewed as the same as the prior art *P. haemolytica* recombinant PlpE, but named differently as recombinant PlpE of '*M. haemolytica*'. Pandher's recombinant *E. coli* PlpE composition is viewed as inherently containing an adjuvant: (a) since *E. coli* is well known in the art to be a Gram negative bacterium which contains the lipopolysaccharide antigen as a part of its cell, and (b) since the lipopolysaccharides have been well known in the art to serve as intrinsic adjuvants. For example, see first paragraph under Example 17

of Hunter; and section [0097] of Berinstein *et al.*

Claims 1-3 are anticipated by Pandher *et al.* Hunter or Berinstein *et al.* is **not** used as a secondary reference in combination with Pandher *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Pandher *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Remarks

12) Claims 1-3 stand rejected.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of after-final amendments is (571) 273-8300.

14) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2004

RESULT 1
 Q9ZHK7
 ID Q9ZHK7 PRELIMINARY; PRT; 356 AA. Seq ID No. 2.
 AC Q9ZHK7;
 DT 01-MAY-1999 (TrEMBLrel. 10, Created)
 DT 01-MAY-1999 (TrEMBLrel. 10, Last sequence update)
 DT 01-MAR-2004 (TrEMBLrel. 26, Last annotation update)
 DE Outer membrane lipoprotein PlpE.
 GN Name=plpE;
 OS Pasteurella haemolytica.
 OC Bacteria; Proteobacteria; Gammaproteobacteria; Pasteurellales;
 OC Pasteurellaceae; Mannheimia.
 OX NCBI_TaxID=75985;
 RN [1]
 RP SEQUENCE FROM N.A.
 RC STRAIN=89010807N;
 RX MEDLINE=99043883; PubMed=9826333;
 RA Pandher K., Confer A.W., Murphy G.L.;
 RT "Genetic and immunologic analyses of PlpE, a lipoprotein important in
 complement-mediated killing of Pasteurella haemolytica serotype 1.";
 RL Infect. Immun. 66:5613-5619(1998).
 DR EMBL; AF059036; AAC82640.1; -
 DR InterPro; IPR005014; Lipoprotein_14.
 DR Pfam; PF03346; Lipoprotein_14; 1.
 KW Lipoprotein.
 SQ SEQUENCE 356 AA; 39129 MW; E66E48DFE87393D7 CRC64;
 Query Match 100.0%; Score 1734; DB 2; Length 356;
 Best Local Similarity 100.0%; Pred. No. 1.7e-97;
 Matches 337; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 Qy 1 CCGSGSGGSSSTPNHPKPVLPKTONNLQAQNVPOAQNASQAQNAPOAQNAPQAQNAPOV 60
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